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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/051,843	06/29/1998	TRACY WILLSON	11373	8485

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EXAMINER	
HOWARD, ZACHARY C	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
08/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/051,843	WILLSON ET AL.	
	Examiner	Art Unit	
	ZACHARY C. HOWARD	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7,10,25,28,29,37,43,44,47-49,53 and 54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 37* is/are allowed.

6)☒ Claim(s) *2,7,10,25,28,29,43,44,47-49,53 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 January 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/15/08;6/2608*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 5/30/08 has been entered in full. Claims 1, 2, 7, 10, 25, 28, 43 and 48 are amended. Claims 8, 30, 36, 38, 45 and 46 are canceled (claims 3-6, 9, 11-24, 26, 27, 31-35, 39-42 and 50-52 were canceled previously). New claims 53 and 54 are added.

Claims 1, 2, 7, 10, 25, 28, 29, 37, 43, 44, 47-49, 53 and 54 are under consideration in the instant application.

Information Disclosure Statement

The Information Disclosure Statements of 5/30/08 and 6/26/08 have been considered.

Withdrawn Objections and/or Rejections

The following page numbers refer to the previous Office Action (2/14/08).

All objections and/or rejections of claims 8, 30, 36, 38, 45 and 46 are moot in view of Applicants' cancellation of these claims.

The objections to claim 1, 2 and 7 at pg 3 are *withdrawn* in view of Applicants' amendments to the claims.

The rejection of claims 1, 2, 7, 10, 25, 28, 29 and 47 under 35 U.S.C. § 112, first paragraph at pg 4-7 for failing to provide enablement for the full scope of the claims is *withdrawn* in view of Applicants' amendments to the claims.

The rejection of claims 1, 2, 7, 10, 25, 28, 29 and 47 under 35 U.S.C. § 112, first paragraph at pg 7-8 for failing to comply with the written description requirement is *withdrawn* in view of Applicants' amendments to the claims.

New rejections necessitated by Applicants' amendment

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 recites the limitation "The isolated nucleic acid molecule of claim 1, encoding a polypeptide consisting of amino acid 28-426 of SEQ ID NO: 4" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Specifically, claim 1 is limited to nucleic acids that comprise "the amino acid sequence set forth in SEQ ID NO: 4"; i.e., claim 1 is limited to nucleic acids that encode a polypeptide comprising the entirety of residues 1-426 of SEQ ID NO: 4. Therefore, this genus does not include nucleic acids encoding polypeptides that consist of shorter fragments of SEQ ID NO: 4 such as residues 28-426. It is noted that claim 1 previously did encompass such nucleic acids, but was amended to delete this recitation. Thus, the nucleic acid recited in claim 44 is no longer encompassed by the genus of parent claim 1. Thus, there is no longer antecedent basis for the nucleic acid recited in claim 44.

Claim 49 recites the limitation "The isolated nucleic acid molecule of claim 1 wherein said sequence consists of nucleotides 142-1086 of SEQ ID NO: 3" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claim 49 lacks antecedent basis for essentially the same reason as claim 44. Residues 142-1086 of SEQ ID NO: 3 only encode residues 28-426 of SEQ ID NO: 4. Thus, the nucleic acid recited in claim 49 is no longer encompassed by the genus of parent claim 1.

Claim Rejections - 35 USC § 112, 1st paragraph, new matter

Claims 2, 10, 25, 28, 29, 43, 47, 48, 53 and 54 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain new matter.

Claim 2 has been amended to recite, "An isolated nucleic acid molecule comprising a nucleotide sequence encoding a derivative of an IL-13 receptor α-chain, wherein said receptor α-chain comprises the amino acid sequence as set forth in SEQ ID NO: 4, and wherein the derivative comprises amino acids 28-342 of SEQ ID NO: 4 or comprises an amino acid sequence having at least 95% identity with amino acids 28-342 of SEQ ID NO: 4, and wherein the derivative binds with IL-13". Claim 2, as amended, contains new matter for the recitation of "the derivative comprises amino acids 28-342 of SEQ ID NO: 4" for two reasons:

(1) The specification does not teach a derivative of an IL-13 receptor α-chain that consists of residues 28-342 of SEQ ID NO: 4.

(2) The specification does not teach derivatives of an IL-13 receptor α-chain that comprises residues 28-342 of SEQ ID NO: 4. Previously, the claim recited a derivative that was limited to an extracellular domain of the IL-13 receptor α-chain. As amended, the claim encompasses longer derivatives (including the transmembrane domain) that comprise residues 28-342 of SEQ ID NO: 4.

Applicants' arguments (6/26/06; pg 6-7) as they pertain to the new matter rejection of amended claim 2 have been fully considered but are not deemed to be persuasive for the following reasons.

In the response, Applicants argue that the amended claim is fully supported by the specification and does not introduce new matter. Applicants argue that the "previous recitation of "amino acids 28-346" of SEQ ID NO: 4 is based on the alignment between the human and murine sequences and on the disclosure of a murine soluble form composed of amino acids 27-344 of SEQ ID NO: 2 (murine receptor) in Example 12 (page 40 of the specification)" (pg 7). Applicants argue that the murine soluble form of Example 12 includes a few amino acids (residues 341-344) of the transmembrane domain shown in Figure 1 in addition to the extracellular domain. Applicants argue that the alignment of Figure 7 shows that residues 28-342 of SEQ ID NO: 4 "correspond to the extracellular domain of the human receptor" (pg 7).

Applicants' arguments have been fully considered but are not found persuasive. The specification does not teach that a derivative consisting of residues 28-342 of SEQ

ID NO: 4 (human sequence) is part of the claimed invention. Furthermore, the specification does not even teach that a derivative consisting of the corresponding residues (27-340) of the mouse sequence (SEQ ID NO: 2) is part of the claimed invention. The specification teaches that the invention includes nucleic acids encoding a "part" of SEQ ID NO: 2 (pg 4, line 29) or SEQ ID NO: 4 (pg 5, line 14), but does not point to any particular "part" of either sequence on these pages. The specification further teaches that a recombinant IL-13 receptor α-chain may be in soluble form, but does not teach any specific residues for this soluble form. The skilled artisan would recognize that a "soluble form" is a genus that includes any variant of SEQ ID NO: 4 that is mutated to render the protein soluble (such as by deleting all or part of the transmembrane domain), and thus does refer to any specific sequence. Example 12 provides a single example of a soluble receptor derived from SEQ ID NO: 2 that is "[t]he mature extracellular part of the NR4 coding region (Thr27 to Thr344)". While this specific example may provide support for a derivative consisting of the exact corresponding residues of the human sequence (Thr28-Thr346), it does not provide support for either a slightly shorter form of the murine (residues 27-340 of SEQ ID NO: 2) or the corresponding human (28-342 of SEQ ID NO: 4) sequences. There is nothing in the specification directing the skilled artisan to these slightly shorter sequences. The specification does not contain any teachings indicating that a derivative consisting of the specific residues corresponding to the isolated extracellular domain of either protein is part of the invention. The only teaching in the specification regarding the use of the extracellular domain of the protein is the specific example in Example 12.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by the record for NCBI GenBank EST Database Accession Number H57074 (10/5/1995; 2 pages as printed).

Claim 7 as amended encompasses an "isolated nucleic acid molecule … comprising a nucleotide sequence which hybridizes to the complement of the nucleotide sequence as set forth in SEQ ID NO: 3 under stringency condition, wherein said stringency condition comprise hybridization in 5x SSC at 50°C and washing in 0.2x SSC at 50°C."

EST H57074 is a 154 nucleotide sequence that has 98.1% similarity to residues 469-623 of SEQ ID NO: 23. An alignment of SEQ ID NO: 3 and EST H57074 is shown here:

```
RESULT 2
H57074
LOCUS       H57074                 154 bp    mRNA    linear   EST 05-OCT-1995
DEFINITION  yz07f11.r1 Soares fetal liver spleen 1NFLS Homo sapiens cDNA clone
            IMAGE:204621 5', mRNA sequence.
ACCESSION   H57074
VERSION     H57074.1  GI:1009906
KEYWORDS    EST.
SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Euarchontoglires; Primates; Catarrhini;
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                Hominidae; Homo.
REFERENCE   1  (bases 1 to 154)
  AUTHORS   Miller,R., Clark,N., Dubuque,T., Hillsion,K., Hawkins,M.,
            Holman,M., Hultman,M., Kucaba,T., Le,M., Lennon,G., Marra,M.,
            Parsons,G., Rifkin,L., Rohlfing,T., Soares,M., Tan,F.,
            Trevaskis,E., Waterston,R., Williamson,A., Wohldmann,P. and
            Wilson,R.
  TITLE     The Washu-Merck EST Project
  JOURNAL   Unpublished (1995)
COMMENT     Contact: Wilson RK
            Washington University School of Medicine
            4444 Forest Park Parkway, Box 8501, St. Louis, MO 63108
            Tel: 314 286 1800
            Fax: 314 286 1810
            Email: est@watson.wustl.edu
            Insert Size: 2571
            High quality sequence stops: 75
            Source: IMAGE Consortium, LLNL
            This clone is available royalty-free through LLNL ; contact the
            IMAGE Consortium (info@image.llnl.gov) for further information.
            Insert Length: 2571   Std Error: 0.00
            Seq primer: M13REV
            High quality sequence stop: 75.
FEATURES    Location/Qualifiers
     source 1..154
            /organism="Homo sapiens"
            /mol_type="mRNA"
            /db_xref="GDB:3773752"
            /db_xref="taxon:9606"
            /clone="IMAGE:324623"
            /sex="male"
            /dev_stage="29 week post conception fetus"
            /lab_host="DH10B (ampicillin resistant)"
            /clone_lib="Soares fetal liver spleen 1NFLS"
            /note="Organ: Liver and Spleen; Vector: pT7T3D (Pharmacia)
            with a modified polylinker; Site_1: Pac I; Site_2: Eco RI;
            1st strand cDNA was primed with a Pac I - oligo(dT) primer
            (5' AACTGGAAGAATTAATACGACTCACTATTTTTTTTTTTTTTT 3'),
            double-stranded cDNA was ligated to Eco RI adaptors
            (Pharmacia), digested with Pac I and cloned into the Pac I
            and Eco RI sites of the modified pT7T3 vector.  Library
            went through one round of normalization. Library
            constructed by Bento Soares and M.Fatima Bonaldo."

  Query Match             10.2%;  Score 140.8;  DB 1;  Length 154;
  Best Local Similarity   98.1%;  Pred. No. 0;
  Matches  152;  Conservative    0;  Mismatches    2;  Indels    1;  Gaps    1;

Qy        469 AACCTGAGCTACATGAAGTGTTCTTGCTCCCTGGAAGCAATACCAGTCCCGACACTAAC 528
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 AACCTGAGCTACATGAAGTGTTCTTGCTCCCTGGAA-GAATACCAGTCCCGACACTAAC 59

Qy        529 TATACTCTCTACTATTGCCACAGAAGCCTTCGAAAAAATTCACTCAACTGTAAAACATCTTT 588
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         60 TATACTCTCTACTATTGCCACAGAAGCCTTCGAAAAAATTCACTCAACTGTAAAACATCTTT 119

Qy        589 AGAGAAGCCAATACTTTGGTTGTTCCTGTATCC 621
              |||||||||||||||||||||||||||||||||
Db        120 AGAGAAGCCAATACTTTGGTTGTCCCTGATCC 154
```

As shown in the alignment, there are two mismatched nucleotides and a single gap of one nucleotide. Due to the small number of mismatches between the two sequences, EST H57074 would hybridize to the complement of SEQ ID NO: 3 under the recited stringency conditions.

Furthermore, EST H57074 comprises numerous shorter sequences with 100% identity to regions of SEQ ID NO: 3. For example, residues 1-20 of H57074 are 100% identical to residues 469-489 of SEQ ID NO: 3. Thus, residues 1-20 represent a

nucleotide sequence that would hybridize to the complement of SEQ ID NO: 3 under the recited stringency conditions. EST H57075 comprises these residues, and thus is a sequence that comprises a nucleotide sequence that could hybridize to the complement of SEQ ID NO: 3 under the recited stringency conditions.

Thus, EST H57074 anticipates claim 7.

Claim 25 encompasses a composition comprising the nucleic acid molecule of claim 7 and a pharmaceutically acceptable carrier. Water is a pharmaceutically carrier. The record for EST H57074 indicates that this nucleic acid was sequence. Sequencing solutions require use of water; thus, the nucleic acid of EST H57074 was inherently placed in water as part of the sequencing protocol. Thus, the record for EST H57074 also anticipates claim 25.

Conclusion

Claims 1 and 37 are allowable.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. C. H./
Examiner, Art Unit 1646

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646